Remarks

Requirement for Information

In the Office Action, the Examiner issued a Requirement for Information under 37 CFR 1.105.

According to MPEP 704.11, a Requirement for Information may only be made when the Examiner has a reasonable basis for requiring the information. Applicants will first respond to the Examiner's reasonable basis, and will then provide a response to the Requirement itself.

A. Reasonableness of the Requirement

In the present Office Action, as Applicants understand it, the Examiner appears to state two bases for the reasonableness of the requirement.

First, the Examiner discovered an old version of the Assignee's web site, which the Examiner says discloses a product called Intelligent Clinical Protocol (iCP). The Examiner has requested "any known publications, brochures, manuals and press releases that describe the clinical protocol modeling software or service that is described by the Fasttrack web site", which the Examiner describes as an iCP product that "was jointly developed with Stanford University and the National Cancer Institute."

Second, the Examiner also discovered an article on the web site of Windhover Information Inc. that indicated that Fasttrack Systems was offering software and services in the clinical trials environment at least as early as December 1999. The Examiner presumed the

December 1999 date from the publication date of the article, not from anything in the article actually stating an offering date. The Examiner therefore has requested "any known publications, brochures, manuals and press releases that describe [the] software or services marketed or developed in 1999 that was the subject of the December 1999 publication".

1. The FastTrack Web Site Does Not Provide a Reasonable Basis for the Examiner's Requirement

Regarding the Fasttrack web site, Applicants would like to point out that neither they nor their assignee FastTrack Systems, offered for sale any "Intelligent Clinical Protocols" prior to Applicants' filing date. As described in great detail in the subject patent application, an iCP is a database that can be constructed and used by Applicants' software, and is specific to the particular protocol being modeled. An iCP is not itself a product that is likely to be offered for sale, and at least prior to Applicants' filing date, neither Applicants nor their assignee had done so.

Also regarding the Fasttrack web site, Applicants would like to point out that the language therein, relied on by the Examiner, does not say that a product "was jointly developed with Stanford University and the National Cancer Institute." The actual language in the web site is that the iCP concept was "[r]ooted in a collaborative effort by Stanford University researchers and the National Cancer Institute." It does not say that the collaborative effort went so far as to include development of the products or concepts now claimed.

In fact, although some basic tools were developed in the context of such a collaborative effort, the iCP concept itself as claimed was developed separately, in the context of a separate

startup company called FastTrack Systems. The collaborative effort was known as Stanford University's Section on Medical Informatics ("SMI"). Some of SMI's technology included *tools* that could be used to implement an iCP according to Applicants' invention, much in the way that Microsoft Word is a *tool* that could be used to enable the writing of a great novel. Just as Microsoft Word does not itself teach or suggest the great novel, neither did SMI's tools teach or suggest an iCP according to Applicants' invention.

Note that one of the inventors named in the present patent application was previously affiliated with SMI, and FastTrack licensed some of SMI's technology to help it implement embodiments of the invention, but again, the iCP concept itself according to Applicants' invention was neither taught nor suggested by these connections.

Accordingly, it can be seen that although the iCP concept according to Applicants' invention may have been "rooted in" some of the previous SMI work, there was in fact no "clinical protocol modeling software or service" that FastTrack Systems "jointly developed with Stanford University and the National Cancer Institute" - and the actual language of the FastTrack web page does not say otherwise.

It might be reasonable for the Examiner to seek descriptions of the SMI technology as potential prior art to aspects of Applicants' invention. However, Applicants believe that the Examiner is already aware of the relevant SMI technology both from the descriptions of it in Applicants' specification (see, e.g., pp. 18-19 of Applicants' specification), as well as from several papers published by SMI personnel and already submitted to the Examiner with previous Information Disclosure Statements. Applicants believe that they have already submitted to the

Examiner all papers published by SMI that they are aware of that are material to the invention claimed in the present patent application and non-cumulative. These papers do not teach or suggest Applicants' invention as claimed.

Accordingly, it is respectfully submitted that the FastTrack web site discovered by the Examiner, though superficially appealing, does not in fact provide a reasonable basis for the Examiner's requirement.

2. The Windhover Information Article Does Not Provide a Reasonable Basis for the Examiner's Requirement

Regarding the Windhover Information article, this report says that "Several other companies, including ... FastTrack Systems, offer software and services...."

However, the report found by the Examiner is only an "Executive Briefing" about the actual article that appeared in In Vivo. As such, it is only a summary of what was actually reported, and in the above-quoted language, is quite imprecise.

Applicants are submitting herewith an Information Disclosure Statement including the full article apparently referred to in this Briefing. FastTrack is discussed primarily at pp. 4-5. Although some excerpts can be taken out of context to suggest that FastTrack's software and services were currently available when the article was published, Applicants respectfully submit that as a whole, the article reveals that they were not. What was being discussed was FastTrack's *plans*, not an actual currently available product or service. In fact, the article includes a paragraph specifically saying this:

> As impressive and promising as FastTrack's plans may sound, it still has to prove that its model will work. It plans to begin beta testing in February 2000 with a selected set of sponsors and sites. Since the iCP incorporates disease-specific information, FastTrack will focus on therapeutic areas, beginning with oncology and adding others over time. (p. 5, col. 1, lines 5-11, emphasis added).

Clearly the article does not state or imply that a FastTrack product or service was currently available as of the article's date of December 1999.

Accordingly, it is respectfully submitted that the Windhover Information summary discovered by the Examiner on the web, though superficially appealing, does not in fact provide a reasonable basis for the Examiner's requirement.

B. Response to Requirement for Information

Even though Applicants do not believe that the Examiner has stated a reasonable basis for the Requirement for Information, Applicants will now respond to the Requirement itself.

The Examiner has required submission of "any known publications, brochures, manuals and press releases that describe the clinical protocol modeling software or service that is described by the Fasttrack web site and specifically what software or services were marketed or developed in 1999 that was the subject of the December 1999 publication."

Pursuant to 37 CFR 1.105(a)(3), however, Applicants hereby state that the information required to be submitted is unknown to Applicants.

More specifically, since "the clinical protocol modeling software or service" that the Examiner asserts "is described by the Fasttrack web site" does not exist, as explained above,

Applicants are not aware of any "publications, brochures, manuals and press releases that describe" any such clinical protocol modeling software or service.

In addition, since the "software or services" that the Examiner asserts "were marketed or developed in 1999 that was the subject of the December 1999 publication" do not exist, also as explained above, Applicants are not aware of any "publications, brochures, manuals and press releases that describe" any such software or services.

Nevertheless, an Information Disclosure Statement is being submitted herewith to cite the full article apparently referred to in the "Executive Briefing" report found by the Examiner. To the extent the Examiner considers this article to teach subject matter material to the application, Applicants respectfully submit that as a publication it is dated too recently to constitute prior art under 35 U.S.C. 102(b). Applicants further submit that because any relevant information in this article derived from Applicants themselves, nor do they constitute prior art under 35 U.S.C. 102(a).

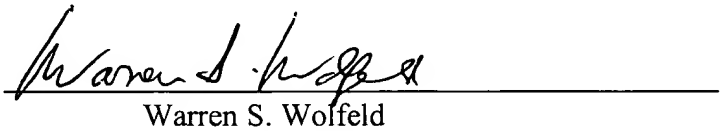
Conclusion

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, since the Examiner has failed to make a *prima facie* case of unpatentability. A Notice of Allowance is therefore requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

Enclosed is a PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136 for extending the time to respond up to and including 14 September 2004.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0869 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: September 14, 2004 By: 

Warren S. Wolfeld
Reg. No. 31,454

Haynes Beffel & Wolfeld LLP
P.O. Box 366
Half Moon Bay, CA 94019
(650) 712-0340 phone
(650) 712-0263 fax